

## Informed Consent and HIPAA Authorization Guidance

What do you want to do? <sup>1</sup>	Screen and/or Recruit Screen/recruit potential participants without obtaining their informed consent to view their medical records.	Consent in Person Conduct a study where you will see participant face to face to determine interest in the research study.	Consent Without Obtaining a Signature Conduct a phone survey or an online or mailed survey / questionnaire.	No Consent Process Retrospective chart review or other scenarios where there is no participant contact.
What this means	No consent process or HIPAA authorization to screen/recruit, but you will seek informed consent (and possibly HIPAA authorization) prior to enrolling the participant into the research study.	You will need to use a written informed consent form and a written HIPAA authorization. You will obtain the participant's signature on both documents.	You will need an informed consent script that contains the elements of informed consent, but you do not obtain the participant's signature. You will request to waive HIPAA authorization.	There is no consent process or HIPAA authorization.
What kind of approval does this need?	ICF: Waiver to screen and/or recruit	ICF: Written informed consent form	ICF: Informed consent script <b>AND</b> a Waiver of Documentation of Informed Consent	ICF: Waiver of informed consent
		If you want to waive or alter some consent elements, you'll need approval to waive/alter consent		
	HIPAA: Waiver to screen and/or recruit	HIPAA: A written HIPAA authorization	HIPAA: Waiver of HIPAA authorization	HIPAA: Waiver of HIPAA authorization
		If you want to waive or alter some HIPAA elements, you'll need approval to waive/alter HIPAA		
Complete these forms	ICF: Waiver or Alteration of the Informed Consent Process <sup>2</sup>	ICF: Durham VAMC ICF template	ICF: 1) Use the Durham ICF template as guide for the script, <b>and</b> 2) Waiver of Documentation of Informed Consent	ICF: Waiver or Alteration of the Informed Consent Process <sup>2</sup>
		If you want to waive/alter elements of informed consent: Waiver or Alteration of the Informed Consent Process <sup>2</sup>		
	HIPAA: Waiver or Alteration of HIPAA Authorization <sup>2</sup>	HIPAA: Durham VAMC HIPAA template	HIPAA: Waiver or Alteration of HIPAA Authorization <sup>2</sup>	HIPAA: Waiver or Alteration of HIPAA Authorization <sup>2</sup>
		If you want to waive/alter HIPAA: Waiver or Alteration of HIPAA Authorization <sup>2</sup>		

<sup>1</sup> You can choose more than one option (e.g., you may screen/recruit and also obtain a written or verbal informed consent)

<sup>2</sup> You can make multiple requests on the Waiver or Alteration requests (e.g., you can request a waiver to screen/recruit and alter the elements of informed consent and/or HIPAA)